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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,915	11/02/2001	Anthony J. Mauro	460.2115USU	7768

7590 11/17/2004

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EXAMINER

ANDERSON, CATHARINE L

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/003,915		MAURO ET AL.	
	Examiner		Art Unit	
	C. Lynne Anderson		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-36 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 10-11, 13-14, 19-23, 25-26, 29-32, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker, Jr. et al. (6,559,189).

Baker discloses a tampon, as described in column 13, lines 53-54, comprising a composition disposed in the tampon, as described in column 7, lines 50-52 and 54-55. The composition comprises an anti-bacterial agent and a finishing agent. The anti-bacterial agent is a quaternary ammonium compound, as described in column 5, line 64, to column 7, lines 12, specifically alkyl dimethyl benzyl ammonium chloride and alkyl dimethyl ethylbenzyl ammonium chloride. The finishing agent is a nonionic surfactant, polyethylene glycol, as described in column 5, lines 54-56 and 62. The composition further comprises a preservative, as described in column 5, lines 22-27. Baker discloses the composition of the claimed invention, and the antibacterial properties are inherent in the chemicals comprising the composition. Baker therefore inherently discloses a composition

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effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth, and fulfills all limitations of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9, 24, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (6,559,189).

Baker discloses the amount of anti-bacterial agent as based on the total weight of the composition, as described in column 30, lines 38-41, invention but remains silent as to the amount of anti-bacterial agent as based on the total weight of the tampon. It would have been obvious to one of ordinary skill in the art at the time of invention to make the tampon of Baker comprising 0.01% to 5% by weight of the anti-bacterial agent, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Claims 12, 17, and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (6,559,189).

Baker discloses the amount of finishing agent as based on the total weight of the composition, as described in column 30, lines 33-33, invention but remains

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silent as to the amount of finishing agent as based on the total weight of the tampon. It would have been obvious to one of ordinary skill in the art at the time of invention to make the tampon of Baker comprising 0.01% to 10% by weight of the finishing agent, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Claims 15-16 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (6,559,189) as applied to claims 14 and 32 above, and further in view of Fischetti et al. (6,335,012).

Baker discloses all aspects of the claimed invention with the exception of the surfactant being a polyoxyethylene fatty acid ester. Baker discloses the surfactant may be a polyoxyethylene sorbital ester, as disclosed in column 5, lines 36-38.

Fischetti discloses polyoxyethylene fatty acid ester and polyoxyethylene sorbital ester as being art-recognized equivalent surfactants, as described in column 11, lines 14-16, which are suitable for use in tampons, as described in column 12, lines 20-21 and 26.

It would therefore be obvious to one of ordinary skill in the art at the time of invention to have the surfactant of Baker comprise a polyoxyethylene fatty acid ester, as taught by Fischetti, since the examiner takes official notice of the equivalence of polyoxyethylene fatty acid ester and polyoxyethylene sorbital

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ester for their use as surfactants in tampons, and the selection of any of these equivalents would be within the level of ordinary skill in the art.

Response to Arguments

Applicant's arguments filed 16 August 2004 have been fully considered but they are not persuasive.

In response to the applicant's argument that Baker discloses the use of oil-in-water emulsions in a variety of medical devices, only one of which is a tampon, it is noted that a reference that clearly names the claimed species anticipated the claim no matter how many other species are claimed (see MPEP 2131.02).

In response to the applicant's argument that Baker fails to disclose the claimed invention, it is noted that Baker discloses providing a medical device, a tampon, with a composition, the composition comprising a quaternary ammonium compound and polyethylene glycol, as described in the rejection under 35 U.S.C. 102(e) above. In other words, Baker discloses all of the components of the claimed invention, which is described in the instant specification as being capable of neutralizing TSST-1 toxin and reducing *Staphylococcus aureus* bacteria growth. The product disclosed by Baker is substantially identical to the claimed product, and therefore will perform the same function as the claimed product. The reactive qualities of the combination of the quaternary ammonium compound and polyethylene glycol are inherent to the structures, and therefore the tampon of Baker will react to neutralize TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth.

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With respect to claims 12, 17, 35, and 36, Baker discloses a system by which the oil-in-water emulsion is delivered by the tampon, as described in column 7, lines 46-56. Baker therefore discloses some amount of the emulsion is deposited on the tampon, but remains silent as to this amount with respect to the total weight of the tampon.

With respect to claims 15, 16, 33, and 34, Fischetti does not deal with bacteria specifically in the mouth and teeth only, and discloses in column 12, lines 20-40, treatment of vaginal bacteria with a tampon.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number

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is (703) 306-5716. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on (703) 308-1412. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

UWA
cla

November 14, 2004



Larry I. Schwartz
Supervisory Patent Examiner
Group 3700